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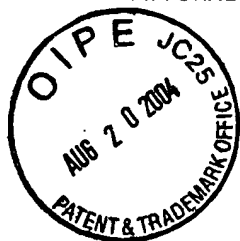
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August 20, 2004

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Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Art Unit 1644

Re: U.S. Utility Patent Application
Application No. 10/690,639; Filed: October 23, 2003
For: **Pharmaceutical Composition of F(ab')₂ Antibody Fragments (As Amended)**
Inventors: de Silanes *et al.*
Our Ref: 2099.0010001/JAG/LAV

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Information Disclosure Statement (3 pp.);
2. Form PTO-1449 listing 34 cited documents (6 pp.);
3. Copies of 10 cited documents; and
4. Return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Commissioner for Patents
August 20, 2004
Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Laura Vogel
for

Laura A. Vogel
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JAG/LAV/rjv
Enclosure

301139_1.DOC



THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

de Silanes *et al.*

Appl. No. 10/690,639

Filed: October 23, 2003

For: **Pharmaceutical Composition of
F(ab')₂ Antibody Fragments (*As
Amended*)**

Confirmation No. 9165

Art Unit: 1644

Examiner: *To be assigned*

Atty. Docket: 2099.0010001/JAG/LAV

Information Disclosure Statement

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450
Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Copies of documents **AA1-AG1, AL1, AR2, AR6, AS1, AS2, AS5, AS6, AT1** and **AT5** were cited by or submitted to the Office in an IDS that complies with 37 C.F.R. § 1.98(a)-(c) in Application No. 09/798,076, filed March 5, 2001, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d). Copies of documents **AH1-AK1** and **AA2-AE2** are not provided in accordance with the U.S. Patent and Trademark Office pre-OG notice of July 11, 2003, which states "[t]he Office hereby waives the requirement under 37 C.F.R. § 1.98 (a)(2)(i) for submitting a copy of each cited U.S. patent and each U.S. patent application publication for all U.S. national patent applications filed after June 30, 2003." A copy of each other document is attached.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits the following, in regards to non-English language document **AL1** cited on Form PTO 1449:

Document **AL1**, Spanish Patent Publication No. 2 106 183, is in the Spanish language. An English language abstract of document **AL1** is cited as document **AT5**.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being submitted before the mailing date of a first Office Action on the merits. No statement or fee is required.


It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

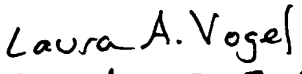
Silanes *et al.*
Appl. No. 10/690,639

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

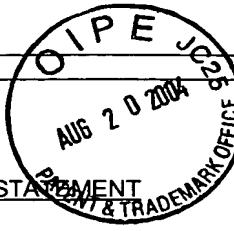

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Registration No. 29,021


Reg. No. 55,702

Date: August 20, 2004

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FORM PTO-1449

INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.
2099.0010001/JAG/LAVAPPLICATION NO.
10/690,639FIRST NAMED INVENTOR
Silanes *et al.*FILING DATE
October 23, 2003ART UNIT
1644

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA1	4,806,346	02/21/1989	Hum <i>et al.</i>			12/16/1986
	AB1	4,814,433	03/21/1989	Fredrickson			09/16/1987
	AC1	4,849,352	07/18/1989	Sullivan <i>et al.</i>			10/09/1984
	AD1	4,940,670	07/10/1990	Rhodes			04/09/1986
	AE1	5,328,834	07/12/1994	Ngo <i>et al.</i>			09/08/1989
	AF1	5,733,742	03/31/1998	Landon			03/10/1995
	AG1	5,888,511	03/30/1999	Skurkovich <i>et al.</i>			12/23/1996
	AH1	6,333,032	12/25/2001	Skurkovich <i>et al.</i>			12/22/1997
	AI1	6,534,059	03/18/2003	Skurkovich <i>et al.</i>			01/28/2001
	AJ1	6,709,655	03/23/2004	López de Silanes <i>et al.</i>			03/05/2001
	AK1	2003/0215448	11/20/2003	Skurkovich <i>et al.</i>			03/14/2003

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL1	2 106 183	11/01/1997	Spain			Yes X No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	1	Cain, B.S., <i>et al.</i> , "The Physiologic Basis for Anticytokine Clinical Trials in the Treatment of Sepsis," <i>J. Am. Coll. Surg.</i> 186:337-351, American College of Surgeons (1998)
	AS	1	Fekade, D., <i>et al.</i> , "Prevention of Jarisch-Herxheimer Reactions by Treatment with Antibodies Against Tumor Necrosis Factor α ," <i>N. Engl. J. Med.</i> 335:311-315, Massachusetts Medical Society (1996)
	AT	1	Fox, D.A., "Cytokine Blockade as a New Strategy to Treat Rheumatoid Arthritis," <i>Arch. Intern. Med.</i> 160:437-444, American Medical Association (2000)

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 2099.0010001/JAG/LAV	APPLICATION NO. 10/690,639
	FIRST NAMED INVENTOR Silanes <i>et al.</i>	
	FILING DATE October 23, 2003	ART UNIT 1644

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA2	2003/0223995	12/04/2003	Skurkovich <i>et al.</i>			11/26/2002
	AB2	2003/0224005	12/04/2003	Skurkovich <i>et al.</i>			02/21/2003
	AC2	2003/0228310	12/11/2003	Skurkovich <i>et al.</i>			11/26/2002
	AD2	2004/0062768	04/01/2004	Skurkovich <i>et al.</i>			08/05/2003
	AE2	2004/0086508	05/06/2004	Skurkovich <i>et al.</i>			07/30/2003
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FOREIGN PATENT DOCUMENTS

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>2</u>	Krueger, J.G., "The immunologic basis for the treatment of psoriasis with new biologic agents," <i>J. Am. Acad. Dermatol.</i> 46:1-23, Mosby (2002)
	AS	<u>2</u>	Lisman, K.A., <i>et al.</i> , "Managing Heart Failure with Immunomodulatory Agents," <i>Cardiol. Clin.</i> 19:617-625, W.B. Saunders Co. (2001)
	AT	<u>2</u>	Luger, T., "Treatment of immune-mediated skin disease: future perspectives," <i>Eur. J. Dermatol.</i> 11:343-347, John Libbey Eurotext (2003), downloaded from: < http://www.john-libbey-eurotext.fr/en/revues/medecine/ejd/e-docs/00/01/88/A6/article.md >

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	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>3</u>	Martin, G.S., "Current Management Strategies for Severe Sepsis and Septic Shock," Presented at Chest 2001: 67th Annual Scientific Assembly of the American College of Chest Physicians, November 4 - 8, 2001, Philadelphia, PA, downloaded from: < http://www.medscape.com/viewarticle/412927 >
	AS	<u>3</u>	Present, D.H., <i>et al.</i> , "Infliximab for the Treatment of Fistulas in Patients with Crohn's Disease," <i>N. Engl. J. Med.</i> 340:1398-1405, Massachusetts Medical Society (1999)
	AT	<u>3</u>	Qian, Y., <i>et al.</i> , "Topical Soluble Tumor Necrosis Factor Receptor Type I Suppresses Ocular Chemokine Gene Expression and Rejection of Allogenic Corneal Transplants," <i>Arch. Ophthalmol.</i> 118:1666-1671, American Medical Association (2000)

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	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>4</u>	Stapczynski, J.S., "Shock, Septic," Dire, D.J., <i>et al.</i> , eds., eMedicine.com Inc., (2004), downloaded from: < http://emedicine.com/EMERG/topic533.htm >
	AS	<u>4</u>	Torres, P.F., and Kijlstra, A., "The role of cytokines in corneal immunopathology," <i>Ocul. Immunol. Inflamm.</i> 9:9-24, Swets & Zeitlinger (2001)
	AT	<u>4</u>	Zhu, S., <i>et al.</i> , "Early Expression of Proinflammatory Cytokines Interleukin-1 and Tumor Necrosis Factor- α after Corneal Transplantation," <i>J. Interferon. Cytokine. Res.</i> 19:661-669, Mary Ann Liebert, Inc. (1999)

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	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>5</u>	Abstract of Dick, A.D., <i>et al.</i> , "Neutralizing TNF- α Activity Modulates T-cell Phenotype and Function in Experimental Autoimmune Uveoretinitis," <i>J. Autoimmun.</i> 11:255-264, Academic Press (1998), downloaded from: < http://80-www.elsevier.com.proxygw.wrlc.org/wps/find/journaldescription.cws_home/622856/description >
	AS	<u>5</u>	International Search Report for International Patent Application No. PCT/MX02/0013, mailed August 16, 2002
	AT	<u>5</u>	Dialog File 351, Accession No. 9271133, Derwent WPI English language abstract for Spanish Patent No. 2 106 183 (Document AL1)

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	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>6</u>	English language translation of Secretaría de Salud, "Potency of Anti-Poison Sera," in <i>Farmacopea de los Estados Unidos Mexicanos</i> , Vol. II, Secretaría de Salud, Mexico City, MX, pp. 1756-1757 (2000)
	AS	<u>6</u>	English language translation of Secretaría de Salud, "Pyrogen Tests," in: <i>Farmacopea de los Estados Unidos Mexicanos</i> , Vol. I, Secretaría de Salud, Mexico City, MX, pp. 334-335 (2000)
	AT		

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